

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----X		
MAMIE THADEN,)	
)	
Plaintiff,)	08-CV-5432 (LAK)
)	
vs.)	
)	
DAVOL INC. and C.R. BARD, INC.,)	
)	
Defendants.)	
)	
-----X		

**ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS
DAVOL INC. AND C.R. BARD, INC.**

Defendants Davol Inc. and C.R. Bard, Inc., (“Defendants”) by and through counsel, answer the Plaintiff’s Complaint (the “Complaint”) as follows:

PARTIES

1. Paragraph 1 of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore deny the same.

2. Davol Inc. (“Davol”) admits that it is organized under the laws of the State of Delaware with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island 02886, and its resident agent in Rhode Island is CT Corporation System located at 10 Weybosset Street, Providence, Rhode Island. Davol further admits that, at certain times, limited manufacturing of the Composix® Kugel® Patch has occurred in Rhode Island.

3. C.R. Bard, Inc. (“Bard”) admits that it is organized under the laws of the State of New Jersey and that Davol is its subsidiary. Bard further admits that it does business in the State of New York. Bard denies the remaining allegations.

JURISDICTION

4. Defendants admit that the requirements of 28 U.S.C. § 1332 have been met.

5. The allegations in Paragraph 5 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

6. The allegations in Paragraph 6 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

FACTS

6. *(Plaintiff's Complaint inadvertently also numbers this paragraph as paragraph 6).* The allegations in Paragraph 6 are not directed to Bard, and therefore no response is required. Davol admits that at various times it designed, distributed, and manufactured the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. As to the remaining allegations contained in Paragraph 6 of the Complaint, Davol lacks sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies the same.

7. The allegations in Paragraph 7 are not directed to Bard, and therefore no response is required. Davol admits that at various times it manufactured the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. Davol does not know what is meant by “delivery”

beyond the meaning of “distributed” which has been admitted therefore it denies the allegation. As to the remaining allegations contained in Paragraph 7 of the complaint, Davol lacks sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

8. Defendants admit that Davol submitted a 510k Application on October 23, 2000. On January 22, 2001, the federal Food and Drug Administration approved Davol’s Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information.

9. Defendants deny the allegations.

10. The Establishment Inspection Report referenced in Paragraph 10 speaks for itself. To the extent any material allegations are alleged, Defendants deny the allegations.

11. The allegations in Paragraph 11 are not directed to Bard, and therefore no response is required. Davol admits that at various times it designed, manufactured, sold, and distributed the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. Davol denies the remaining allegations of this paragraph.

12. Defendants deny the allegations.

13. The Establishment Inspection Report referenced in Paragraph 13 speaks for itself. To the extent any material allegations are alleged, Defendants deny the allegations.

14. Defendants admit that the federal Food and Drug Administration characterizes a “Class I” recall as “there is a reasonable chance that the product will cause serious health problems or death.”

15. Defendants admit that a limited voluntary recall of certain larger-sized Composix® Kugel® Hernia Patches took place in late 2005, early 2006, and early 2007. Defendants further state these products have since been returned to the market with FDA approval.

16. Defendants admit that a limited voluntary recall of certain larger-sized Composix® Kugel® Hernia Patches took place due to a potential for PET recoil ring breaking. Davol further admits that it has received reports of ring migration, intestinal fistulae, bowel perforation, and death.

17. The Establishment Inspection Report referenced in Paragraph 17 speaks for itself. To the extent any material allegations are alleged, Defendants deny the allegations.

18. Defendants admit that a limited voluntary recall of certain larger-sized Composix® Kugel® Hernia Patches took place in late 2005, early 2006, and early 2007. Defendants further state these products have since been returned to the market with FDA approval.

19. Defendants admit that a limited voluntary recall of certain larger-sized Composix® Kugel® Hernia Patches took place in late 2005, early 2006, and early 2007. Defendants further state these products have since been returned to the market with FDA approval.

20. The allegations in Paragraph 20 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

21. The allegations in Paragraph 21 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

22. Defendants deny the allegations.

23. Defendants deny the allegations.

24. Defendants deny the allegations.

25. Defendants deny the allegations.

26. Defendants deny the allegations.

27. Defendants deny the allegations.

28. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint and therefore deny the same.

29. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint and therefore deny the same.

30. The allegations in Paragraph 30 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

31. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 31 of the Complaint and therefore deny the same.

COUNT I
Negligence

32. In response to Paragraph 32 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

33. The allegations in Paragraph 33 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

34. The allegations in Paragraph 34 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

35. The allegations in Paragraph 35 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

36. The allegations in Paragraph 36 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

37. The allegations in Paragraph 37 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

38. The allegations in Paragraph 38 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

39. The allegations in Paragraph 39 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

40. The allegations in Paragraph 40 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

41. The allegations in Paragraph 41 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

42. The allegations in Paragraph 42 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT II
Strict Product Liability

43. In response to Paragraph 43 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

44. The allegations in Paragraph 44 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

45. Davol admits that at various times it designed, manufactured, distributed, and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. As to the remaining allegations contained in Paragraph 45 of the complaint, Davol does not know what is meant by “assembled” or “conveyed” beyond the meanings of “manufactured” and “distributed” which have been addressed above. Davol accordingly denies the remaining allegations. Bard denies each and every allegation presented in Paragraph 45.

46. The allegations in Paragraph 46 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

47. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.

48. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.

49. The allegations in Paragraph 49 and its subparts (i) through (x) are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

50. The allegations in Paragraph 50 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT III
Negligent Infliction of Emotional Distress

51. In response to Paragraph 51 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

52. The allegations in Paragraph 52 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

53. The allegations in Paragraph 53 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

54. The allegations in Paragraph 54 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

55. The allegations in Paragraph 55 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

56. The allegations in Paragraph 56 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT IV
Intentional Infliction of Emotional Distress

57. In response to Paragraph 57 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

58. The allegations in Paragraph 58 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

59. The allegations in Paragraph 59 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

60. The allegations in Paragraph 60 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

61. The allegations in Paragraph 61 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

62. The allegations in Paragraph 62 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT V
Breach of Implied Warranty

63. In response to Paragraph 63 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

64. The allegations in Paragraph 64 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

65. The allegations in Paragraph 65 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

66. The allegations in Paragraph 66 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

67. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny those allegations.

68. The allegations in Paragraph 68 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

69. The allegations in Paragraph 69 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT VI
Failure to Warn

70. In response to Paragraph 70 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

71. Davol admits that at various times it designed, manufactured, and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. As to the remaining allegations contained in

Paragraph 71 of the complaint, Davol lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Davol therefore denies the allegations. Bard denies each and every allegation presented in Paragraph 71.

72. The allegations in Paragraph 72 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

73. The allegations in Paragraph 73 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

74. The allegations in Paragraph 74 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

75. The allegations in Paragraph 75 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

76. The allegations in Paragraph 76 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

77. The allegations in Paragraph 77 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

COUNT VII **Fraud**

78. In response to Paragraph 78 of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

79. Davol admits that at various times it designed, manufactured, and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. Bard denies these allegations.

80. The allegations in Paragraph 80 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

81. The allegations in Paragraph 81 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

82. The allegations in Paragraph 82 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

83. The allegations in Paragraph 83 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

84. The allegations in Paragraph 84 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

85. The allegations in Paragraph 85 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against Defendants upon which relief can be granted.

2. Plaintiff's Complaint should be dismissed for lack of proper venue.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment k, bar Plaintiff's claims against Defendants in whole or in part.

4. The doctrines contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar Plaintiff's claims against Defendants in whole or in part.

5. The doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims bar Plaintiff's claims against Defendants in whole or in part.

6. Applicable statutes of limitations, statute of repose, and the doctrine of laches bar Plaintiff's claims in whole or in part.

7. Plaintiff's, or Plaintiff's agents', including Plaintiff's physicians', misuse or abnormal use of the product or failure to follow instructions bar Plaintiff's claims in whole or in part.

8. If Plaintiff used a product sold by Defendants, then Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

9. Any alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

10. If Plaintiff sustained any damages or injuries, which is denied, then such damages and injuries were caused or contributed to by the acts, omissions or fault of Plaintiff, including contributory negligence, contributory fault, comparative fault, assumption of the risk, or failure to mitigate damages.

11. If Plaintiff used a product sold by Defendants, Plaintiff used the product for off-label purposes, which bars the Plaintiff's claims.

12. The learned intermediary doctrine bars Plaintiff's claims.

13. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

15. Plaintiff's claims are preempted, in whole or in part, by applicable federal law.

16. Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical conditions.

17. If Plaintiff suffered injuries or damages as alleged, which is denied, such injuries or damages resulted from acts or omissions of persons or entities for which Defendants are neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Defendants. Such acts or omissions on the part of other persons or entities, such diseases and/or such causes constitute an independent, intervening and sole proximate cause of Plaintiff's alleged injury or damages.

18. Defendants state that if Plaintiff sustained any damages or injuries, which is specifically denied, such damages or injuries were caused by the acts, omissions or fault of Plaintiff or others, for whose conduct these Defendants are not responsible; accordingly, they are entitled to an assessment of the relative degree of fault for all such persons and entities.

19. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by the Bard® Kugel® Patch, which is denied, were the result of Plaintiff's own idiosyncratic reactions.

20. Plaintiff failed to mitigate damages, which limits Plaintiff's recovery, if any, in whole or in part.

21. Defendants have no legal relationship or privity with Plaintiff and owe no duty to Plaintiff by which liability could be attributed to it.

22. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff failed to give notice of any breach thereof. Moreover, Defendants effectively and fully disclaimed any warranty, express or implied, in the sale of any product for which they are responsible in this matter.

23. Plaintiff's claims are barred in whole or in part by Plaintiff's own comparative negligence.

24. Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff received from collateral sources.

25. If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Defendants' product.

26. At the time the product at issue, the Bard® Kugel® Patch, left the custody and control of Defendants, there was no defect in said product that either caused or contributed to any injuries or damages that Plaintiff may have suffered, if any.

27. The applicable state and federal law, including *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), bars Plaintiffs' alleged claims for punitive or exemplary damages. Permitting recovery of punitive or exemplary damages in this case would violate Defendants' rights as reserved by the Fifth, Seventh, Eighth, and

Fourteenth Amendments to the United States Constitution, and related provisions of the United States Constitution, as well as the applicable due process guarantees of the Arizona Constitution.

28. To the extent that the applicable state law permits the jury and Courts to measure punitive or exemplary damages by the net worth or financial status of Defendants and imposes greater punishment on defendants with greater net worth, such an award would be unconstitutional because it permits arbitrary punishment, allows bias and prejudice to infect the verdict, and allows dissimilar treatment of similarly situated defendants, all in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the similar provisions of the Arizona Constitution.

29. To the extent Plaintiffs' Complaint seeks punitive damages, such claims are barred because Plaintiffs have failed to allege conduct warranting the imposition of punitive damages under Arizona, and/or other applicable laws.

30. To the extent Plaintiff's Complaint seeks punitive damages, applicable federal law preempts any such claim, in whole or in part.

31. Plaintiff's claims are, in whole or in part, subject to adjudication under the laws of states or jurisdictions other than New York.

32. Defendants hereby give notice that they intend to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserve their right to amend this Answer to assert such defenses.

WHEREFORE, Defendants Davol Inc. and C.R. Bard, Inc. demand judgment in their favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

PLEASE TAKE NOTICE that answering Defendants hereby demand a trial by jury as to all issues.

Dated: July 10, 2008

Respectfully submitted,

PEPPER HAMILTON LLP

By: /s/ Samuel J. Abate, Jr.

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CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2008, a copy of the foregoing Answer, Affirmative Defenses, and Corporate Disclosure Statement has been made upon the following in the manner listed below:

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BY: /s/ Samuel J. Abate, Jr.
Samuel J. Abate, Jr.